



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/091,759 | 03/05/2002 | Adnan M. M. Mjalli | 41305/271123 | 6863 |

7590 07/29/2003

Cynthia B. Rothschild
Kilpatrick Stockton LLP
1001 West Fourth Street
Winston-Salem, NC 27101

EXAMINER

O SULLIVAN, PETER G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1621 | |

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | |
|--------------------------------------|-------------------------------------|
| Application No. 10/091,759 | Applicant(s) Adnan et al. |
| Examiner Peter O'Sullivan | Art Unit 1621 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 7, 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7 and 11-62 is/are pending in the application.

4a) Of the above, claim(s) 2-7, 11, 13-17, 19-40, 46-48, 52-55, and 57-60 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 41-45, 49-51, 56, 61, and 62 is/are rejected.

7) Claim(s) 12 and 18 is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

6) Other:

Art Unit: 1621

1. Claims 1-7 and 11-62 are pending in this application which should be reviewed for errors.

In response to the requirement for the election of a single disclosed species, applicants elected with traverse the compound of example 8. Applicants' non-heterocyclic fluorenyl containing urethanes not further ortho-fused, sulfur, nitro or silicon substituted are examined therewith with all other compounds withdrawn. Accordingly, claims 2-7, 11, 13-17, 19-40, 46-48, 52-55 and 57-60 are held withdrawn.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 41-45, 49, 50, 51, 56, 61 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds substituted by the listed groups, does not reasonably provide enablement for all substitution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants' Markush groups use the term, "comprising," which opens the groups to substitution such as phosphorus containing groups, lithium atoms, etc. Applicants are requested to use the phrase, "selected from the group consisting of" or a similar phrase instead.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1621

5. Claims 1, 41-45, 49, 50, 51 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The two definitions for G1 are overlapping.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kalindjian et al., Tsukita et al., Sivanandaiah et al., and Pirkle et al. Kalindjian et al. disclose 5-[[2-[[9H-fluoren-9-ylmethoxy)carbonyl]amino]-3-(4-iodophenyl)-1-oxopropyl]amino]-bis(1,1-dimethylethyl) 1,3benzenedicarboxylic acid ester. Tsukita et al., Sivanandaiah et al., and Pirkle et al. also disclose anticipating compounds (s. abstracts).

8. Claims 1 and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Kchucholowski et al. who disclose [2-[[2,6-bis(1-methylethyl)phenyl]amino]-2-oxo-1-(phenylmethyl)ethyl]-, 9H-fluoren-9-ylmethyl carbamic acid ester and other anticipating compounds, (s. examples).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1621

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 41-45, 49-51, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chucholowski et al. Chucholowski et al. disclose compounds of formula I useful in treating atherosclerosis (Col. 1, l. 65 - Col. 6, l. 24). R13 may be fluorenyl and anticipating compounds are disclosed. The instant invention differs from the teaching of Chucholowski et al. in that not all of applicants' compounds are exemplified although more are generically disclosed. It would have been prima facie obvious at the time the invention was made to one of ordinary skill in the art to start with the teaching of Chucholowski et al., to make further compounds of applicants especially in view of anticipating compounds already made and to expect to produce anti-atherosclerotic compounds.

11. Claims 12 and 18 are allowable, but objected to as dependent on a rejected claim.

12. Any inquiry concerning this communication should be directed to Peter O'Sullivan at telephone number (703) 308-4526.



PETER O'SULLIVAN
PRIMARY EXAMINER
GROUP 1200